

FEB 28 1997

K964863

**Section 510(k) Premarket Notification
Summary of Safety and Effectiveness
Information**

**For The Model 45E, Model 45EH, Model
RX-100, Mark VIII, Mark IX, Mark X and
Model Etelna II Dental Hand-engines and
Controllers**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Trade Name:

Model 45E Handengine & Controller
Model 45EH Handengine & Controller
Model RX-100 Handengine & Controller
Model Etelna II Handengine & Controller
Model Bravo G-7 Handengine & Controller
Mark VIII - Controller
Mark IX - Controller
Mark X - Controller

Common Name: Dental hand-engine & controllers

Classification Name: Dental handpiece and accessories

2. Establishment Name & Registration Number:

Name: BELL INTERNATIONAL, INC.

Number: 2921268

3. Classification:

§ 872.4200 Dental handpiece and accessories. (a) Identification. A dental handpiece and accessories is an AC-powered, water-powered, air-powered, or belt-driven, hand-held device that may include a foot controller for regulation of speed and direction of rotation or a contra-angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. (b) Classification. Class I. [55 FR 48439, Nov. 20, 1990].

Product Code(s): 76EBW

Device Class: Class I

Classification Panel: Dental

4. Equivalent / Predicate Device(s):

1. The 25-D hand engine and C-310 Console (Controller)

5. Description of the Device:

This submission covers the BELL INTERNATIONAL, INC. series of electric dental hand-engines. BELL INTERNATIONAL, INC. offers a complete line of electric motor drive hand-engines for dental restoration and surgical applications.

The present BELL INTERNATIONAL, Inc. line of hand-engines is made up of the following devices:

MODEL	SPEED	TORQUE	VOLTAGE	DIMEN.	WGHT.	CHUCK
The 25D	20K RPM	320gm/cm	20 VDC	22x146mm	150 gm.	2.35mm
The 45E	20K RPM	320gm/cm	30 VDC	21x168mm	150 gm.	2.35mm
The 45EH	30K RPM	400gm/cm	30 VDC	24x168mm	150 gm.	2.35mm
The RX-100	30K RPM	400gm/cm	30 VDC	24x168mm	160 gm.	2.35mm
The Etelna II	20K RPM	270ma/cm	12 VDC	23x140mm	160 gm.	2.35mm
The Bravo G-7	20K RPM	270ma/cm	12 VDC	23x140mm	160 gm.	2.35mm

The table below details the controller used with each hand-engine and any secondary hand-engines that are compatible.

Console Controller	Primary Hand-engine	Console Speed Rating	Maximum Output	Secondary Hand-engine(s)
C-310 Console	25D	To 20K RPM	20 VDC	NA
C-361 Console	45E	To 20K RPM	30 VDC	45EH, RX-100
C-361 Console	45EH	To 30K RPM	30 VDC	45E, RX-100
RX-100 Console	RX-100	To 30K RPM	30 VDC	45E, 45EH
Mark VIII Console	45EH	To 30K RPM	30 VDC	RX-100
Mark IX Console	45EH	To 30K RPM	30 VDC	RX-100
Mark X Console	45EH	To 30K RPM	30 VDC	RX-100
Etelna II Console	Etelna II	To 20K RPM	12 VDC	Bravo G-7
Bravo G-7 Console	Bravo G-7	To 20K RPM	12 VDC	Etelna II

All engines have controllers equipped with Off/On and/or variable speed foot switches. The hand-engines accept various available "E-type connector" angled and straight front-handpieces produced by many different manufacturers. The different E-type front-handpieces are designed to do different types of dental work or surgical procedures. This includes those front-handpieces that multiply or reduce terminal shaft speed. The front-handpieces that are compatible with the Bell line of hand-engines are industry standard items and are covered by separate 510(k)s held by the manufacturers of those items.

12. Comparison to Predicate Device(s):

The 25-D hand engine and its attendant C-310 Console sold by Bell International, Inc. is a documented preamendment device and is the substantially equivalent comparison device for this submission. Each subsequent hand-engine and controller represent only minor variants of the original engine and controller.

There are essentially two main differences between the original device and the newer models. The original model contained a 20 VDC motor and the newer models contain a 30 VDC and 12 VDC. The original model accepted "D-type" front-handpiece connectors while the newer ones accept the more common "E-type" connectors. Two of the new models also operate at higher speed, 30,000 vs. 20,000 RPM and have marginally more torque.

Other than the minor performance differences, the new controllers and hand-engines are substantially equivalent to the parent Model 25-D **hand engine** with C-310 Console. The Model 25D is a pre-amendment device, having been in commercial distribution since 1972.

The Model 25D along with its minor modification models, (the Mark VI-0 controller and the 45E hand-engine) has operating speeds of approximately 400 rpm to 20,000 rpm.

The 45E hand-engine was the first minor modification of the original design. It is the same basic 25D engine altered to accept the "E-type" handpiece connectors and was able to operate on 30 VDC current. The 45E produced the same amount of torque as the 25-D **hand engine** and had the same indications for use as well.

The 45EH and the RX-100 models are essentially the same as the 45E but produce more torque than either the original 25-D **hand engine** or the 45E. The 25D and the 45E offered 320 gram centimeters torque and the 45EH and RX-100 provide 400 gram centimeters torque. The 45EH and RX-100 also provide higher maximum RPM. Motor speeds for the 25D and 45E were limited to approximately 20,000 RPM and the 45EH and RX-100 can operate as high as 30,000 RPM. The indications for use remain unchanged.

The last change, incorporated into the Etelna II and the Bravo G-7, were to produce a lower cost "bare bones" unit that offered essentially the same level of performance as the 25D and the 45E. This was accomplished by using a lower cost 12 VDC motor. The Etelna II unit is also a portable battery operated unit while the Bravo G-7 unit is a wall current/transformer based unit.

The Mark VIII Controller is a space saving unit designed to be built into existing Air Power consoles located in the dentists office and will operate either the 45EH or the RX-100. The Mark IX unit operates the 45EH and has slightly increased power output of 35 VDC for Endodontic procedures. The Mark X is a space saving all inclusive foot-switch controller.

7. Modified Device Data:

Not applicable to this device. This submission covers a new device not a modified device.

8. Applicant / Sponsor Name / Address:

BELL INTERNATIONAL, INC.
31 Edwards Court
Burlingame, CA 94010

9. Contact Person:

Mr. Dewey Bell
BELL INTERNATIONAL, INC.
31 Edwards Court
Burlingame, CA 94010
(415) 348-2055
(415) 348-3937

10. Manufacturing Facility:

At the present time, all devices and controllers are purchased from recognized medical device manufacturers of handengines and controllers. All product specifications are checked and final QC inspections are conducted in-house by BELL INTERNATIONAL, INC.

Comparison Table:

FEATURE	25-D handengine w/C-310 Console	The Etelna II	Bravo G-7	The RX-100	The 45 EH	The 45E	SE?
Intended Use	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Engine, power supply and controller for dental handpiece	Yes
Forward & reverse switch	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Engine torque	320 gram centimeters	270 m/a max.	270 m/a max.	400 gram centimeters	400 gram centimeters	320 gram centimeters	Yes
Automatic Torque Limiting	No	No	No	No	No	Yes	No
Direct - remote selector switch	Yes	No	Yes	Yes	Yes	Yes	Yes
Speed Control	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Power Supply	110-115 VAC, 50/60 Hz	12 VDC via Battery & AC Charger	12 VDC via 110-115 VAC, 50/60 Hz Transformer	110-115 220-230 VAC, 50/60 Hz	110-115 VAC, 50/60 Hz	110-115 VAC, 50/60 Hz	Yes
UL/ETL Compliant	Yes - UL-544	Yes - UL-544	Yes - UL-544	Yes - UL-544	Yes - UL-544	Yes - UL-544	Yes
Console Model Compatible	C-310	Etelna II	Bravo G-7	C-361, Mark VIII & RX-100 Bat. Pack	C-361, Mark VIII, Mark IX & Mark X	C-361	Yes
Can be used with irrigation	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Digital speed readout	No	No	No	No	No	No	Yes
Voltage output	2 - 20 volts DC	12 VDC	12 VDC	3 - 30 VDC	3 - 30 VDC	3 - 30 WDC	Yes

12. Safety Standards:

All engines and controllers are designed to meet UL-544 (medical device) requirements for electrical safety.

13. Sterilization Information:

The device may not be sterilized. Surface disinfecting of the console, cords, foot switch and hand engine, cords and tubing may be accomplished using a number of available non-solvent based commercial germicidal or surface disinfectant preparations. Only the front handpiece of the dental drill may be sterilized.